EXHIBIT 2

TO AFFIDAVIT OF SAMUEL N. LONERGAN

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

DECLARATION OF GREGORY K. BELL, PH.D.

SUBMITTED IN SUPPORT OF DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

February 8, 2007

1. My name is Gregory K. Bell. I am an Executive Vice President at CRA International ("CRA"), an economics and management consulting firm. My education includes a master's of business administration and a doctorate in business economics, both from Harvard University. Details of my professional experience, publications, and past testimony are described in my curriculum vitae, a copy of which is attached as Exhibit A. CRA receives compensation for my time at a rate of $700 per hour. Neither CRA nor I has any financial interest in the outcome of this litigation.

2. For the past twelve years, I have directed the Pharmaceuticals practice within the Business Consulting platform at CRA. In this capacity, I have led many projects concerning the economics of business strategy in the pharmaceutical industry. Most of my work has focused on product pricing, contracting strategy for managed care organizations and hospitals, influences on physician prescribing behavior, and product launch strategy. In addition, I have submitted numerous expert reports and given testimony in a wide range of cases involving patent disputes, licensing, antitrust and other issues in the pharmaceutical industry. As a result of my experience as both a consultant to pharmaceutical companies and an expert witness in litigation matters, I have developed a familiarity with relevant aspects of the industry bearing on economics or business strategy.

3. With respect to *In re Pharmaceutical Industry Average Wholesale Price Litigation* (the "AWP litigation"),[1] Professor Fiona Scott Morton (Professor of Economics at the Yale School of Management and an expert on the economics of the pharmaceutical industry) and I prepared an expert tutorial entitled, "An Orientation to the Acquisition of and Reimbursement for Prescription Drugs," submitted on December 3, 2004 ("Tutorial") on behalf of the Track 1 Defendants, and I provided testimony to the Court on December 7, 2004, in connection with that Tutorial. I also submitted expert reports on behalf of the Track 1 Defendants dated March 22 and November 26, 2006, and on behalf of Bristol-Myers Squibb, dated March 15 and November 17, 2006; I testified at trial on November 28, December 7, and December 8, 2006. Additionally, I submitted a report on behalf of certain defendants on class certification in *Robert J. Swanston v. TAP Pharmaceutical Products, Inc., et al.* (Cause No. CV2002004988, State of Arizona), as well as affidavits on behalf of defendant Roxane Laboratories, Inc. in *State of Connecticut v. Dey Inc., et al.* (Docket No. TTD-X07-CV-03 0083296S),

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[1] MDL No. 1456, Civil Action No. 01-12257-PBS, United States District Court of Massachusetts.

on behalf of defendant Pharmacia Corporation in *State of Connecticut v. Pharmacia Corporation* (Docket No. X07 CV03-0083297 S), and on behalf of certain defendants in *State of Alabama v. Abbott Laboratories, Inc., et al.* (Civil Action No. 2005-219, Circuit Court of Montgomery County).

4. I have been asked by counsel for the Defendant manufacturers to supply this declaration in support of their motions for summary judgment in connection with: *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM, and *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR.

I. PHARMACEUTICALS AT ISSUE AND THEIR PRICING

5. The pharmaceutical products at issue can be classified along two dimensions: whether they are self- or physician-administered, and whether generic versions of a branded product are available. Each of these characteristics can affect the pricing, price concessions, and distribution of the drug in question.

6. The first dimension that differentiates drugs is the manner by which drugs are administered. In general, self-administered drugs ("SADs") are dispensed by retail pharmacies,[2] mail order pharmacies, or hospital pharmacies, and the patient is responsible for taking the drug.[3] Alternatively, physician-administered drugs ("PADs") are commonly dispensed by physicians, who are also responsible for administering these drugs to their patients.

7. Most of the drugs sold in the United States are self-administered and dispensed through pharmacies, which generally purchase pharmaceutical products from wholesalers or directly from manufacturers. In the case of SADs, a patient receives a prescription for a given drug from his or her physician, takes the

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[2] I include pharmacy sections of food, mass-merchant, and other retail establishments under the term "retail pharmacies."

[3] There are a few self-administered drugs for which the mode of administration is injection.

prescription to a pharmacy, and obtains the drug from the pharmacy.[4] The pharmacy may then be reimbursed by the third-party payor ("TPP") according to the patient's insurance coverage.

8. PADs are not generally distributed through retail pharmacies, although in some cases patients may acquire physician-administered drugs from retail pharmacies and bring them to a physician's office for administration (a process known as "brown-bagging"). Rather, physicians typically purchase PADs from a wholesaler or specialty distributor, administer them to patients, and receive reimbursement from the TPP, a process known as "buy & bill."

9. Drugs are also typically classified as single- or multi-source. Single-source, or "branded," drugs are sold under a brand name, are typically available from only one company, and are generally patent-protected.[5] Multi-source drugs are those for which generic equivalents are available, because these are not patent-protected and are available from multiple companies.[6]

10. Manufacturers of single-source SADs compete to be the product prescribed by a physician and reimbursed by a TPP.[7] Retail pharmacies generally must dispense prescriptions for single-source SADs as written.[8] Pharmacists do not expect to receive price concessions on these purchases and manufacturers do not normally offer them. Because pharmacists have little or no ability to influence market

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4 The patient may be required to make a co-payment or co-insurance payment to the pharmacy.

5 Single-source drugs are also referred to as innovator products. Patent-protected drugs can only be manufactured and sold by the patent holder or under a license from the patent holder.

6 Generic drugs are usually not sold under a trade name, but rather under the name of the active ingredient.

7 TPPs benefit from this competition by receiving rebates from the drug manufacturers in order for a specific drug to be placed in a preferred position on the formularies used to influence prescribing practices for the members of the health plans administered by the TPPs. Physicians, however, are not involved in the financial aspects of SAD transactions.

8 No states allow a pharmacist to substitute a therapeutic alternative (i.e., a different drug (chemical compound) approved by the Food and Drug Administration to treat the same condition); a physician first would have to write a new prescription if a retail pharmacy were to dispense an alternative single-source SAD to a patient.

share for single-source SADs, it would not make sense for manufacturers to attempt to increase the difference between AWP and acquisition cost (i.e., the "spread") on these drugs to benefit the pharmacists, as I understand the Plaintiffs are alleging.[9]

11. Manufacturers of single-source PADs that do not face significant therapeutic or generic competition generally have no incentive to offer significant price concessions on their products. As with single-source SADs, single-source PADs may face competition from other products in the same therapeutic category. In these situations, those purchasers that can influence market share, including dispensing physicians, gain leverage in negotiating price concessions. Physician office practice characteristics such as size and reputation affect the ability to obtain price concessions from manufacturers.

12. Retail pharmacies generally carry only one manufacturer's version of a multi-source drug. As a result, manufacturers compete to have their generic versions of multi-source SADs be the products stocked by pharmacies. Retail pharmacies, therefore, are often able to extract price concessions from generic manufacturers.

13. As with multi-source SADs, manufacturer pricing strategies for multi-source PADs vary widely. Manufacturers recognize that some physicians will continue to purchase the innovator product at pre-generic prices, while others will search for the product with the lowest acquisition cost. The result can be significant variation in the net price realized by the manufacturers of PADs subject to generic competition.

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[9] Manufacturers would also have no reason to increase the "spread" in order to induce physicians to prescribe their single-source SADs, as physicians are not involved in the financial aspects of the transaction.

II. MEDICAID REIMBURSEMENT FOR PHARMACEUTICALS

14. Although Medicaid is administered jointly by the federal and state governments, Medicaid reimbursement policy for pharmaceuticals was determined solely by the state agencies prior to 1975.[10]

15. In 1974, the federal Department of Health, Education, and Welfare ("HEW," later the Department of Health and Human Services or "HHS") proposed that Medicaid agencies reimburse pharmacies at their actual acquisition costs for single-source drugs.[11] HEW abandoned this idea because of concerns about pharmacy difficulties with recordkeeping and the administrative problems of tracking deferred and cumulative discounts to pharmacies.[12] Instead, HEW recommended that Medicaid agencies were to reimburse for single-source drugs based on estimated acquisition costs ("EACs"), which commonly were based on AWPs, and to reimburse for multi-source drugs based on what they termed maximum allowable cost ("MAC").[13] The final regulations implemented in 1975 stated that the upper limit for reimbursement of prescription drugs was set at "the lowest of: (1) the MAC established for the drug, if any, … plus a reasonable dispensing fee; (2) the [estimated] acquisition cost of the drug plus a reasonable dispensing fee; or (3) the provider's usual and customary charge to the general public for the drug."[14]

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10 The Department of Health, Education, and Welfare noted in its proposed Medicaid regulations, "Some States reimburse providers on the basis of published wholesale prices; others pay on the basis of published prices less a volume discount to the program; still others pay the actual cost to the provider." (See 39 Fed. Reg. 40302 (November 15, 1974), at 40303. An extract from these regulations is attached as Exhibit B.)

11 39 Fed. Reg. 40302 (November 15, 1974), at 40303.

12 40 Fed. Reg. 32283 (July 31, 1975), at 32293. An extract from these regulations is attached as Exhibit C.

13 OIG, *Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs*, A-06-96-00030, April 10, 1997, p. 1. An extract from this report is attached as Exhibit D.

14 40 Fed. Reg. 32283 (July 31, 1975), at 32294.

16. In addition, HEW recognized that "pharmacists may be receiving inadequate compensation for their professional services in dispensing drug products" and required states to conduct surveys regarding the costs of dispensing drug products in order "to assure that established fees are equitable."[15] Furthermore, the conforming regulations for the Social and Rehabilitation Service and Public Health Service state, "The dispensing fee should be ascertained by analysis of pharmacy operational data which include such components as overhead, professional services, and profits."[16]

17. In July 1987, the Health Care Financing Administration ("HCFA")[17] replaced the Federal MAC program with the Federal Upper Limit ("FUL") program.[18] The FUL program set an aggregate limit on drug spending for multi-source drugs equal to "150 percent of the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules …."[19] In addition, HCFA set an upper limit on aggregate spending for non-FUL, generally single-source, drugs based on the lower of such drugs' EAC plus a dispensing fee or the pharmacy's usual and customary charge.[20] While many Medicaid agencies

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15 40 Fed. Reg. 32283 (July 31, 1975), at 32294.

16 40 Fed. Reg. 34515 (August 15, 1975), at 34516. An extract from these regulations is attached as Exhibit E.

17 Currently known as the Centers for Medicare and Medicaid Services ("CMS"), HCFA was created in 1977 to administer both the Medicaid and Medicare programs.

18 52 Fed. Reg. 28648 (July 31, 1987). An extract from these regulations is attached as Exhibit F.

19 52 Fed. Reg. 28648 (July 31, 1987), at 28653. The FUL program allowed individual reimbursement amounts to vary from the FUL for the drug, provided that, on balance, spending was no more than what would be obtained if all drugs were reimbursed at their FULs.

20 52 Fed. Reg. 28648 (July 31, 1987), at 28654-655. Under these regulations, states were no longer required to perform dispensing-fee surveys, however, "[w]e expect that most States will continue their present activities to establish a reasonable dispensing fee level and will document these and any new activities in their State plan. Such activities could include: (1) Audits and surveys of pharmacy operation costs; (2) compilation of data regarding professional salaries and fees; and (3) analysis of compiled data regarding pharmacy overhead costs, profits, etc." (See 52 Fed Reg 28648 (July 31, 1987), at 28651-28652.) Over time, the dispensing fee components of the reimbursement have fallen short of fully compensating costs incurred by pharmacists. (See Schondelmeyer, Stephen W., and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices, Final Report*, Prepared for Deirdre Duzor, CMS, August 30, 2004, p. 5. An extract from this report is attached as Exhibit G.) As a result, pharmaceutical

continued to define EAC based on AWP, other agencies may base their computation of EAC on WAC or other list prices.[21]

18. Exhibit J shows the FUL rates and average AWPs for a number of generic drug products in 1996.[22] This exhibit demonstrates that FULs are often substantially lower than the average generic AWP (the average discount from AWP was 50.3 percent and the highest such discount was 91.3 percent) and that there is not a consistent relationship between the two measures.

I declare under penalty of perjury that this declaration is true and correct.

Gregory K. Bell

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reimbursement rates (i.e., the AWP-based reimbursement for the drug) have had to compensate for this shortfall in dispensing fees, thereby requiring that pharmaceutical reimbursements exceed pharmacies' acquisition costs.

21 For example, the Maryland Medicaid agency's definition of EAC could be based on any of AWP, WAC, or direct price. (See NPC, Pharmaceutical Benefits Under State Medical Assistance Programs, 2000. An extract from this report is attached as Exhibit H.) Commercial insurers, manufacturers, pharmacies, and other participants in the pharmaceutical industry also use list prices. (See e.g., CBO, "*Prescription Drug Pricing in the Private Sector*, January 2007, p. 9. An extract from this report is attached as Exhibit I.)

22 This exhibit includes all drugs included in Exhibit A to State of Montana's Second Amended Complaint, August 1, 2003, for which FULs had been set in 1996, except for topically-applied products. Many other drugs listed in Montana's Exhibit A have had FULs set since 1996. I understand that the drugs included in Exhibit J are also at issue in the Nevada case, so that these FULs, which are applied nationally, would apply in Nevada as well.

EXHIBIT A

GREGORY K. BELL

Executive Vice President

Ph.D. Business Economics,
Harvard Graduate School of Arts and Sciences/
Harvard Graduate School of Business Administration

M.B.A. Harvard Graduate School of Business Administration

B.A. Simon Fraser University

Dr. Bell, executive vice president at CRA International, is responsible for CRA's business consulting platform and he is also the practice leader for pharmaceuticals. In addition, he is a principal member of the firm's Finance, Intellectual Property, and Transfer Pricing practices. As an expert witness, Dr. Bell frequently testifies on damages in intellectual property, finance, and antitrust litigation. Dr. Bell's business consulting engagements focus on the economics of business strategy, working with firms to develop sustainable competitive advantages in specific product markets. He has led and consulted to numerous projects concerning game theory and competitive strategy, global launch strategy, product pricing and positioning, capital budgeting and real options, and cost-benefit analyses.

EXPERIENCE

Business

1992–Present *Executive Vice President*, CRA International, Boston, MA

- Dr. Bell is responsible for CRA's global business consulting practices.
- Dr. Bell directs CRA's global Pharmaceuticals practice.

1987 *Management Consultant*, Alliance Consulting Group, Boston, MA

- Dr. Bell designed a market research program for a consumer electronics client's new product development.

1986 *Associate*, Corporate Finance, Wood Gundy, Vancouver, Canada

- Dr. Bell participated in drafting the prospectus and in marketing the initial public offering of a sportswear manufacturer.

1982–1985 *Chartered Accountant*, Pannell Kerr Forster, Victoria, Canada

- Dr. Bell provided financial accounting, auditing, taxation, and related management consulting services, focusing on special projects involving accounting theory, financial forecasts, and business valuations.

- He also developed a course to prepare the national firm's articling students for the uniform final examination, an examination required to receive the designation of chartered accountant.

- Dr. Bell placed eighth in Canada on the 1983 uniform final examination and was named to national honor roll.

Academic

1991–1992 *Visiting Assistant Professor*, Economics Department, Northeastern University.

- Dr. Bell was responsible for undergraduate courses in industrial organization, managerial economics, and principles of microeconomics.

1991–1992 *Lecturer*, Economics Department, Harvard University.

- Dr. Bell developed the senior-level undergraduate course, "Economics of Business Strategy."

Section Leader, Economics Department, Harvard University.

- Dr. Bell led sections in industrial organization.

1990–1991 *Research Associate*, Economics Department, Harvard University.

- Dr. Bell conducted mergers and acquisitions analysis.

1982 *Research Assistant*, Economics Department, Simon Fraser University.

- Dr. Bell performed capital markets analysis.

PUBLICATIONS

"Global Pricing Strategies for Pharmaceutical Product Launches." With P. Rankin and T. Wilsdon. Chapter 2 of *The Pharmaceutical Pricing Compendium*, pp. 13–23, Urch Publishing Ltd, 2003.

"Cost Implications of Low Molecular Weight Heparins as Prophylaxis Following Total Hip and Knee Replacement." With S. Goldhaber. *Vascular Medicine* (February 2001).

"Economic Outcomes Analysis of Implantable Cardioverter Defibrillators." With M. Stanton. *Circulation* (March 2000).

"Clinical Realities and Economic Considerations: Economics of Intrathecal Therapy." With Samuel J. Hassenbusch et al. *Journal of Pain and Symptom Management* (September 1997).

"Cost-Effectiveness Analysis of Spinal Cord Stimulation in Treatment of Failed Back Surgery Syndrome." With D. Kidd and R. North. *Journal of Pain and Symptom Management* (May 1997).

"Irreversible Investments and Volatile Markets: A Study of the Chemical Processing Industry." With J. Campa. *Review of Economics and Statistics* (February 1997).

"Volatile Exchange Rates and the Multinational Firm: Entry, Exit, and Capacity Options." In L. Trigeorgis (ed.), *Real Options in Capital Investment*. Westport, CT: Praeger, 1995, pp. 163–181.

"Innovation in Cardiac Imaging." With S. Finkelstein and K. Neels. *Medical Innovation at the Crossroads,* Volume 5. Washington, DC: Institute of Medicine, National Academy Press, 1995, pp. 125–154.

"Illustrative Case Problem." With D. Wright. Chapter 13 in Deloris R. Wright, *U.S. Transfer Pricing Guide: Practice and Policy*. CCH, 1995.

"Irreversible Investments and Volatile Exchange Rates: Theory and Evidence." Ph.D. Thesis, Harvard University, 1992.

PRESENTATIONS

"Damages: Lost Profits, Consequential Damages, Damages for Non-Patented Items, Best Practices for the Use of Experts." Panel participant for The Fifth Annual Sedona Conference on Patent Litigation, Sedona, AZ, October 2004.

"Patent Damages: Engineering and Regulatory Work-Arounds." Calculating and Proving Patent Damages, Law Seminars International, Reston, Virginia, June 14, 2004.

"Pricing Strategy and the Product Line." Pricex 2003, Chicago, IL, June 11, 2002.

"Reasonable Royalties for Emerging Technologies." Chaired Panel for The Third Annual Sedona Conference on Patent Litigation, Sedona, AZ, November, 2002.

"Does Price Matter? Pricing, Game Theory, and the Economics of Business Strategy." Pricex 2002, Chicago, IL, April 30, 2002.

"eCommerce and Strategy for the Pharmaceuticals Industry." Chairman for The Canadian National e-Pharma Summit II, Toronto, Canada, June 26–27, 2001.

"Exports and Flexible Production Technologies in Volatile International Markets." 4th Annual Conference on Real Options, Cambridge, UK, July 7–8, 2000.

"The Valuation of Oil Drilling Rights: A Real Options Case Study." 2nd Annual Conference on Real Options, Chicago, IL, June 11–12, 1998.

"Prejudgment Interest." Conference: Charles River Associates' Economists' Perspectives on Antitrust Today—Session: Topics in Calculating Damages, Boston, MA, April 30, 1998.

"Designing Licenses that Maximize Client Profits." American Intellectual Property Law Association Spring Meeting, Minneapolis, MN, April 23, 1998.

"Economics of Therapy." Nonmalignant Pain Management Roundtable, Memphis, TN, January 9, 1997.

"How to Structure Risk-Sharing Contracts to Put Teeth in Disease Management." Congress on Health Outcomes and Accountability, Washington, DC, December 10–13, 1995.

Balancing Low and High Risk Projects." Institute for International Research, Portfolio Planning & Management Conference, Philadelphia, PA, October 23–25, 1995.

"Capitated Pricing for Pharmaceuticals." Medical Marketing Association National Meeting, Monterey, CA, June 1995.

"Evaluating the Cost-Effectiveness of Pharmaceuticals." Anti-Rheumatic Guidelines and International Society for Rheumatic Therapeutics, Scottsdale, AZ, May 1995.

"The Role of Pharmacoeconomics in the Drug Approval Process." Anti-Rheumatic Guidelines and International Society for Rheumatic Therapeutics, Scottsdale, AZ, May 1995.

"Compliance with Section 482." With D. Wright. Institute for International Research, *Practical Approaches to Transfer Pricing* conference, New Orleans, LA, February 22–23, 1995.

"XYZ Corporation: A Case Study in Transfer Pricing." With D. Wright. Institute for International Research, *Practical Approaches to Transfer Pricing* conference, New Orleans, LA, February 22–23, 1995.

"Medtronic's Spinal Cord Stimulation Systems: Reimbursement and Marketing Strategy." Sloan School, Massachusetts Institute of Technology, Cambridge, MA, June 1993.

"Exports and Production Technology under Volatile Exchanges Rates." Stanford University, Stanford, CA, February 1992.

"Capacity and Volatile Exchange Rates: A Study of the Chemical Processing Industry." London Business School, London, United Kingdom, March 1991; University of Michigan, Ann Arbor, MI, March 1991; University of British Columbia, Vancouver, BC, February 1991; Kellogg School of Management, Northwestern University, Evanston, IL, January 1991.

TESTIMONY

Affidavit on behalf of Respondent in the matter of *Warren Lammert, et al.* (January 2007). United States of America, Securities and Exchange Commission, Administrative Proceeding, File No. 3-12386.

Affidavit and testimony on behalf of Respondent in the matter of *Teva Neuroscience G.P.-S.E.N.C. and the medicine "Copaxone"*. (January, February 2007). Patented Medicine Prices Review Board, Ottawa, Canada.

Expert reports on behalf of Barr Pharmaceuticals, Inc., et al. in *Federal Trade Commission and State of Colorado v. Warner Chilcott Holdings Company III, LTD., et al.*, (December 2006, January 2007). United States District Court for the District of Columbia, Civil Action Nos: 05-2179 (CKK) and 05-2182 (CKK).

Expert report and deposition testimony on behalf of MedImmune, Inc. in *Biosynexus, Inc. v. Glaxo Group Limited and MedImmune, Inc.*, (November 2006, January 2007). Supreme Court of the State of New York, County of New York, Index No. 604485/05,

Expert report on behalf of Plaintiffs in *TAP Pharmaceutical Products, Inc., et al.* v. *Atrix Laboratories, Inc., et al.* (October and November 2006). United States District Court, Northern District of Illinois, Case No. 03-C-7822.

Affidavit on behalf of Defendants in *State of Alabama* v. *Abbott Laboratories, Inc., et al.* (September 2006). Circuit Court of Montgomery County, Alabama, Civil Action No. 2005-219.

Expert report on behalf of Plaintiffs in *GlaxoSmithKline Holdings (Americas) Inc. et al.* v. *Commissioner of Internal Revenue* (August 2006). United States Tax Court, Docket Nos. 5750-04 and 6959-05.

Expert report and testimony on behalf of Respondent in *Roche Diagnostics GmbH* v. *SmithKline Beecham Pharma GmbH & Co. KG* (July, November 2006). ZCC Arbitration No. 516.

Affidavit on behalf of Pharmacia Corporation in *State of Connecticut* v. *Pharmacia Corporation* (May 2006). Superior Court of Connecticut, Complex Litigation Docket at Tolland, Docket No. X07-CV-03 0083297S.

Affidavit on behalf of Roxane Laboratories, et al. in *State of Connecticut* v. *Roxanne Laboratories, et al.* (May 2006). Superior Court of Connecticut, Complex Litigation Docket at Tolland, Docket No. TTD-X07-CV-03 0083296S.

Expert Report on behalf of Defendant in *Affinion Loyalty Group, Inc.* v. *Maritz, Inc.* (April 2006). United States District Court, District of Delaware, Civil Action No. 04-360.

Expert report, affidavit and testimony on behalf of Bristol-Myers Squibb in *Pharmaceutical Industry Average Wholesale Price Litigation* (March, November, December 2006). United States District Court, District of Massachusetts, Civil Action No. 01-CV-12257-PBS.

Expert report and deposition testimony on behalf of Plaintiff in *LoJack Corporation v. Clare, Inc.* (December 2005, January 2006, March 2006). Commonwealth of Massachusetts Superior Court, Civil Action No. 03-00627.

Expert report and deposition testimony on behalf of Defendant in *PHT Corporation v. Invivodata, Inc.* (November, December 2005). U.S. District Court of Delaware, C.V. No. 04-60 GMS.

Expert report and deposition testimony on behalf of Defendant in *PHT Corporation v. CRF, Incorporated* (November, December 2005). U.S. District Court of Delaware, C.V. No. 04-61 GMS.

Expert reports and testimony on behalf of GlaxoSmithKline Inc. in *Her Majesty The Queen v. GlaxoSmithKline* (October 2005, January, April 2006). Tax Court of Canada, Court File No. 98-712(IT)G.

Expert report and deposition testimony on behalf of Plaintiffs in *IVPCare, Inc.v. Harvard Pilgrim Health Care, Inc.* (October, November 2005). Superior Court Department of the Trial Court, Commonwealth of Massachusetts, Civil Action No. 03-5058-BLS.

Expert reports and deposition testimony on behalf of Plaintiffs in *Pharmacia & Upjohn Company, LLC v. Sicor Inc., et al.* (September 2005, February, April, October 2006). U.S. District Court of Delaware, C.A. No. 04-833 (KAJ).

Expert reports and deposition testimony on behalf of Wyeth, Inc. in *Applera Corporation et al.* v. *Wyeth, Inc.* (August, September, October 2005). Circuit Court for Montgomery County, Maryland, Civil Action No. 242761.

Expert reports and deposition testimony on behalf of Defendant Medco Health Solutions, Inc., et al. in *U.S. Government* v. *Merck-Medco et al.* (August, September, October, November 2005). U.S. District Court, Eastern District of Pennsylvania, No. 00-CV-737.

Expert reports and deposition testimony on behalf of Defendant FMC Corporation in *Microcrystalline Cellulose Antitrust Litigation* (April, May, June 2005). U.S. District Court, Eastern District of Pennsylvania, Master File No. 01-CV-111 (O'Neill, J.) MDL No. 1402.

Expert report on behalf of Defendants in *Robert J. Swanston* v. *TAP Pharmaceutical Products, Inc., et al.* (February 2005). Superior Court of the State of Arizona in and for the County of Maricopa, Cause No. CV2002-004988.

Expert reports on behalf of Joint Services International, B.V. in *Joint Services International, B.V.* v. *O'Neill, Inc.* (January, April 2005). London Court of International Arbitration, LCIA Arbitration No. 3513.

Expert report and deposition testimony on behalf of Defendants in *RoseMarie Ryan-House, et al.* v. *GlaxoSmithKline, et al.* (December 2004). United States District Court, Eastern Division of Virginia, Civil Action No. 2:02cv442.

Expert reports, tutorial, affidavit and testimony on behalf of Fast Track Defendants in *Pharmaceutical Industry Average Wholesale Price Litigation* (December 2004 and March, November, December 2006). United States District Court, District of Massachusetts, Civil Action No. 01-CV-12257-PBS.

Expert report and deposition testimony on behalf of Yangtze Optical Fibre and Cable Company Ltd. in *Yangtze Optical Fibre and Cable Company LTD.* v. *Lucent Technologies Inc.* (November 2004, March 2005). United States District Court, District of Massachusetts, Civil Action No. 03CV11413EFH.

Expert report and deposition testimony on behalf of Defendants in *Medtronic Vascular, Inc.* v. *Boston Scientific Corporation, et al.*, (July, August 2004). United States District Court, District of Delaware, Civil Action No. 98-478 SLR.

Expert report and deposition testimony on behalf of Mylan Laboratories, Inc., et al., in *Lorazepam & Clorazepate Antitrust Litigation* (May, June 2004). United States District Court, District of Columbia, MDL No. 1290 (TFH).

Affidavit on behalf of Novopharm Limited in *Pfizer Canada et al.* v. *The Minister of Health and Novopharm Limited* (May 2004). Federal Court, Court File No. T-2448-03.

Expert report and deposition testimony on behalf of Bayer AG and Bayer Corporation in *Ciprofloxacin Hydrochloride Antitrust Litigation* (April, May 2004). United States District Court, Eastern District of New York, Master File No. 1:00-MD-1383.

Affidavit and testimony on behalf of Novopharm Limited in *Merck & Co et al.* v. *The Minister of Health and Novopharm Limited* (April, August 2004). Federal Court, Court File No. T-1627-03.

Expert report and deposition testimony on behalf of SRU BioSystems et al. in *Corning Incorporated et al.* v. *SRU BioSystems et al*. (April, May 2004). United States District Court, District of Delaware, Civil Action No. 03-633-JJF.

Expert reports and testimony on behalf of Respondent in *Roche Diagnostics GmbH* v. *SmithKline Beecham (Cork) Ltd* (January, April, July 2004). ZCC Arbitration No. 362.

Expert report and testimony on behalf of Hans-Werner Hector in *Hans-Werner Hector* v. *The Bank of America Corporation et al.* (January, April 2004). American Arbitration Association.

Expert report on behalf of Enzo Biochem, Inc. in *Enzo Biochem, Inc.* v. *Gen-Probe, Inc. et al.* (December 2003). United States District Court, Southern District of New York, Civil Action No. 99-4548 (AKH).

Expert report on behalf of Defendants in *Truitt Enterprises et al.* v. *Union Security Life Insurance Company et al.* (November 2003). United States District Court, District of Maryland (Northern Division), Civil Action No. 03-1422.

Expert report and deposition testimony on behalf of Plaintiffs in *DataSafe, Inc. et al.* v. *Federal Express Corporation et al.* (August 2003, January 2004). Commonwealth of Massachusetts, Superior Court Department, Civil Action No. 01-2590.

Expert report on behalf of SmithKline Beecham Animal Health Inc. in *SmithKline Beecham Animal Health Inc.* v. *Her Majesty The Queen* (July 2003). The Court of Queen's Bench, File No. 95-1077 (IT) G.

Expert report on behalf of Bayer Corporation in *Cipro Cases I & II* (June 2003). Superior Court of the State of California, County of San Diego, JCCP. Proceeding Nos. 4154 and 4220.

Expert reports and deposition testimony on behalf of Defendants in *Johnson Matthey Inc.* v. *Research Corporation, et al.* (March, April 2003). United States District Court, Southern District of New York, Case No. 01-CV-8115 (MBM).

Expert report and deposition testimony on behalf of Bayer AG in *Anne Cunningham, et al.* v. *Bayer AG, et al.* (March, April 2003). Supreme Court of the State of New York, County of New York, Index No. 603820-00.

Expert reports and deposition testimony on behalf of Plaintiff in *Star Scientific* v. *R.J. Reynolds Tobacco Company* (January, March 2003, October 2004). United States District Court for the District of Maryland, Southern Division, Case No. AW 01-CV-1504 and AW 02-CV-2504.

Expert report and deposition testimony on behalf of Defendants in *Tyco Adhesives LP* v. *Olympian Tape Sales, Inc. et al.* (August, October 2002). United States District Court, District of Massachusetts, Civil Action No. 00-11965-NG.

Expert report on behalf of Defendant in *Cook Incorporated* v. *Boston Scientific Corporation* (August 2002). United States District Court for the Northern District of Illinois, Eastern Division, Civil Action No. 01-CV-9479.

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Expert report on behalf of Defendants in *Frederick F. Buechel, M.D. and Michael J. Pappas, Ph.D.* v. *John N. Bain, John G. Gilfillan, III et. al.* (March 2002). Supreme Court of the State of New York County of New York, No. 106963/95.

Expert reports and deposition testimony on behalf of Defendants in *National Rural Electric Cooperative Association et al.* v. *Breen Capital Services Corporation et al.* (February 2002, October 2004). United States District Court of New Jersey, Civil Action No. 2:00cv00722.

Expert report on behalf of Aesculap in *Aesculap AG & Co. et al.* v. *Walter Lorenz Surgical, Inc.* (November 2001). United States District Court for Northern District of California, No. C00-02394-MJJ.

Certification on behalf of Defendants in *Louise Garretson et al.* v. *CSFBTLC Trust II et al.* (October 2001). United States Superior Court for the District of New Jersey, No. HUD-L-3117-00.

Expert report and trial testimony on behalf of C.R. Bard, Inc., in *N.M.T. Medical, Inc.* v. *C.R. Bard, Inc.* (April 2001). American Arbitration Association, AAA Case No. 11 199 00973 00.

Expert report and trial testimony on behalf of Boston Scientific Corp., et al. in *Boston Scientific Corp. et al.* v. *Medtronic AVE, Inc.* (March and April 2001). American Arbitration Association, AAA File No. 50 T 133 00307 00.

Expert report and deposition testimony on behalf of Defendants in *DuPont Pharmaceuticals, et al.* v. *Molecular Biosystems, Inc., et al.* (January and February 2001). United States District Court for the District of Delaware, Civ. No. 99-273 (JJF).

Expert reports on behalf of BASF in *Sawgrass Systems, Inc.,* v. *BASF Corporation* (December 2000, January 2001). United States District Court for the District of South Carolina, Civ. 2:98-3574-11 and 2:99-912-1.

Expert reports and deposition testimony on behalf of Plaintiffs in *Apothecon, Inc., et al.* v. *Barr Laboratories, Inc., et al.* (November 2000, April 2001, June 2005, January, February, March 2006). United States District Court for the District of Southern New York, No. 98 Civ. 0861 (RWS) and No. 99 Civ. 3687 (RWS).

Expert report on behalf of Wold Trona Company, Inc., in *Wold Trona Company, Inc.* v. *SNC-Lavalin America, Inc., et al.* (October 2000). United States District Court for the District of Wyoming, Civ. No. 00CV-1008B.

Expert reports, deposition testimony, and trial testimony on behalf of SciMed Life Systems, Inc., and Boston Scientific Corporation in *Cordis Corporation* v. *Advanced Cardiovascular Systems, Inc., et al.* (August, November, and December 2000). United States District Court for the District of Delaware, Civ. No. 97-550-SLR.

Expert reports and deposition testimony on behalf of SciMed Life Systems, Inc., and Boston Scientific Corporation in *Cordis Corporation* v. *Boston Scientific Corporation and SciMed Life Systems Inc.* (August and November 2000). United States District Court for the District of Delaware, Civ. No. 98-197-SLR.

Expert report and deposition testimony on behalf of SciMed Life Systems, Inc., and Boston Scientific Corporation in *Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation* v. *SciMed Life Systems, Inc. and Boston Scientific Corporation* (November and December 1999). United States District Court for the District of Indiana, IP 98-1108-C-H/G.

Affidavit on behalf of Novopharm Ltd. in *Apotex Fermentation Inc. and Apotex Inc.* v. *Novopharm Ltd. et al.* (October 1999). The Court of Queen's Bench, File No. CI 93-01-73733.

Expert report and deposition testimony on behalf of Bausch & Lomb, Inc., in *Disposable Contact Lens Antitrust Litigation* (July 1999, August 1999). United States District Court for the District of Florida, 94-MDL 1030-J-20A.

Expert reports and trial testimony on behalf of Procter & Gamble Inc. in *Unilever PLC et al.* v. *Procter & Gamble Inc. et al.* (January 1999, December 1999). Federal Court of Canada, T-2534-85.

Expert report for mediation submitted on behalf of Breen Capital in *City of Jersey City* v. *Breen Capital* (December 1998). Superior Court of New Jersey, C-57-98.

Expert reports, deposition testimony, and trial testimony on behalf of Braintree Laboratories, Inc., in *Braintree Laboratories, Inc.,* v. *Nephro-Tech, Inc., et al.* (November 1998, September 1999, June 1999, October 1999). United States District Court for the District of Kansas, 96-CV-2459.

Expert report on behalf of Artegraft, Inc., in *Ethicon Inc. and Johnson & Johnson Consumer Products Inc.* v. *Artegraft, Inc.* (September 1998). American Arbitration Association, File 18-199-00136-96.

Expert report and deposition testimony on behalf of Astro-Valcour, Inc., in *The Dow Chemical Corporation* v. *Astro-Valcour, Inc.* (June 1998, July 1998). United States District Court for the Northern District of New York, 95-CV-1357.

Expert reports and deposition testimony on behalf of Glaxo Wellcome in *Emory University* v. *Glaxo Wellcome* (February 1998, August 1998, September 1998). United States District Court for the Northern District of Georgia, 96-CV-1754.

Expert reports and deposition testimony on behalf of Glaxo Wellcome in *Emory University* v. *Glaxo Wellcome* (November 1997, March 1998, April 1998). United States District Court for the Northern District of Georgia, 96-CV-1868.

Expert reports on behalf of American Home Products in *Johnson & Johnson* v. *American Home Products* (June 1996). United States District Court for the Eastern District of Pennsylvania, 94-CV-1388.

Testimony on behalf of Novo Nordisk in *Genentech, Inc.* v. *Novo Nordisk A/S et al.* (May 1996). United States District Court for the Southern District of New York, 96-CV-1755.

CONSULTING PROJECTS

Antibiotics

- Pricing and managed care strategy to support launch of quinolone. Market research with managed care and physicians.
- Evaluation of European reimbursement environment for launch of quinolone.
- Managed care strategy for quinolone. Market research with managed care.
- Pricing and managed care strategy to support launch of ketolide. Market research with managed care and physicians.

Blood Products

- Cost-effectiveness study for anti-clotting product.
- Strategy for anti-anemia product as it faces competing entry. Market research with managed care, physicians, hospitals, and patients. Address new Medicare policies regarding ASP and CAP.
- Pricing and managed care strategy for anti-clotting product facing competing entry. Market research with managed care and physicians.
- Reimbursement issues for clotting factor.

Cardiovascular Products

- Managed care contracting strategy for statins. Market research with physicians.
- Capitated pricing strategy for statins.
- Pricing and managed care strategy to support global launch of a new class of cardiovascular products for the treatment of hypertension and heart failure. Markets include US, Canada, Europe. Market research with managed care and physicians.
- Managed care strategy for anti-platelet product.

CNS Products

- Pricing and managed care strategy to support launch of prescription pain product. Market research with managed care, physicians and patients.
- Managed care strategy to support dissolving formulation of anti-psychotic.

- Strategy review for Alzheimer's product.
- Managed care strategy for insomnia product facing competitive entry. Market research with managed care.
- Managed care strategy and salesforce training to support launch of depot formulation of anti-psychotic. Market research with managed care.
- Managed care strategy to protect opioid analgesic business as product goes generic. Market research with managed care and physicians.
- Managed care strategy to support franchise products for the prevention and treatment of migraines.
- Managed care strategy to support anti-psychotic franchise confronting competing entry, generic penetration, and preparation for launch of second-generation product. Market research with managed care.
- Pricing and managed care strategy to support the launch of a long-acting opioid. Market research with managed care, physicians and patients.
- Opportunity assessment for new patch product for Alzheimer's disease. Markets include US and Europe. Market research with managed care, physicians and care-givers.

Endocrinology

- Managed care strategy to support the launch of extended-release and combination diabetes products.
- Pricing and managed care strategy to support launch of menopause product. Market research with managed care and physicians.
- Pricing and managed care strategy to support launch of an orphan drug product for Gaucher's disease. Market research with managed care, physicians and patients.
- Advise on global pricing for growth hormone anticipating competitive entry.

Gastro-Intestinal Products

- Cost-effectiveness study of GI impact of NSAIDs.
- Capitated pricing strategy for H2 antagonists.
- Managed care strategy and salesforce training to support the launch of PPI. Market research with managed care and physicians.

- Capitated pricing strategy for PPI.
- Impact of launch of competing PPI. Market research with managed care and physicians.
- Impact of PPI going generic.

Nutritionals

- Value of government (WIC) contracts in the infant formula business. Study covered all aspects of recommendation and consumption behavior and all aspects of manufacturing and distribution, including shelf facings at drug stores, mass merchandisers and super-markets. Market research focused on purchasing and consumption behavior.
- Advise on bid pricing strategy for government contracts.
- Advise on likely exit strategy of competitor.
- Optimal size for ethical salesforce, calling on hospitals and pediatricians.
- Design program for private-sector leadership to combat low-birthweight.
- Assess opportunity for new manufacturing facility and packaging options.
- Advise on likely entry strategy of potential competitor.
- Pricing strategy across product line. Market research with consumers.
- Evaluate opportunity to purchase pumps and plastics business for enteral feeding.
- Assess value of a patient / consumer regarding awareness / trial / usage. Market research involving patients.
- Assess value of hospital contracts for feeding systems in Canada. Market research involving patients and hospitals.

Oncology

- Strategy for second-generation oncolytic as predecessor product goes generic. Market research with physicians and hospitals.
- Strategy for oncolytic as it goes generic. Market research with physicians and hospitals.
- Pricing and managed care strategy to support the launch of a second-generation oncolytic. Market research with physicians and hospitals.
- Diagnostic strategy for breast cancer. Market research with physicians.

- Contracting strategy alternatives to support the launch of an oncolytic.

Rheumatology

- Managed care strategy to support the launch of a new indication.
- Global opportunity assessment for a pipeline product. Particular focus on payer receptivity in US, Canada, France, UK.
- Competitive strategy analysis for rheumatoid arthritis treatment. Market research with physicians, managed care, and specialty pharmacy.

Other

- Pricing and managed care strategy to support the launch of a prescription facial hair removal product.
- Managed care strategy to support incontinence product. Market research with managed care, physicians and patients.
- Managed care strategy to support the launch of a product for premature ejaculation. Market research with managed care, physicians and patients.
- Distribution strategy for a specialty pharmacy asthma product.
- Global valuation of technology for eyecare company.

General Strategy

- Evolution of managed care and its impact on the pharmaceutical industry.
- Strategy for the retail pharmacy.
- Innovations in managed care contracting.
- Assessment of B2B e-commerce strategy for the pharmaceutical industry.
- Contracting for all manufacturer products with major US PBM.
- Strategy for Medicare Part D.
- Tender pricing strategy and implementation. Pilot test covers Mexico, Brazil, Taiwan, Australia, UAE.

Public Policy

- Forced conversion to OTC status.
- Innovation in the pharmaceutical industry: Opportunities for Europe.
- Reference pricing and the impact on innovation for the pharmaceutical industry in Europe.
- Assessment of the comparative costs of branded and generic pharmaceutical companies with respect to reference pricing in Germany.
- Comparative analysis of access to innovative pharmaceutical products. Countries covered include: US, Australia, Canada, France, Germany, UK.
- Assess efficiency of European distribution and generics regimes in France, Germany, Italy, Spain, and UK.

HONORS AND AWARDS

Dean's Doctoral Fellow, Harvard Graduate School of Arts and Sciences/ Harvard Graduate School of Business Administration.

George Baker Scholar, John Thayer Scholar, Frank Knox Memorial Fellow, McKenzie King Traveling Scholar, Harvard Graduate School of Business Administration.

Governor General's Gold Medal, Gordon Shrum Scholar, Simon Fraser University.

EXHIBIT B

federal register

November 15, 1974—Pages 40247–40489

FRIDAY, NOVEMBER 15, 1974

WASHINGTON, D.C.

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PART I

HIGHLIGHTS OF THIS ISSUE

This listing does not affect the legal status of any document published in this issue. Detailed table of contents appears inside.

A REMINDER:

The Office of the Federal Register is located at 1100 L St., NW., but the mailing address is:

Office of the Federal Register
National Archives and Records Service
General Services Administration
Washington, D.C. 20408

(Continued inside)

PART II:

prices. Studies of drug prices in the multiple-source market indicate that savings of 23 to 36 percent would result from the dispensing of lower cost equivalent products. This would be equivalent to savings of 5 to 8 percent of overall prescription drug expenditures.

II. Drug Quality

The existence of different prices for the same drug has raised questions about differences in quality and effectiveness. The Department has an obligation to see that all drugs, not just those potentially cost-reimbursable in Federal programs, are formulated to be safe and effective and are manufactured under optimal conditions to assure consistently high quality. The most important measures the Department employs to achieve these goals are the quality assurance regulations and programs developed under the Food, Drug, and Cosmetic Act. These include stringent requirements for drug testing and clinical experience reporting, as well as quality control assurances prior to approval for marketing. The Department, through the Food and Drug Administration, maintains an extensive drug surveillance program designed to assure adherence to drug standards. This program includes batch certification of antibiotics, insulin, and other selected drugs which the drug surveillance program has revealed to vary significantly from official standards.

The Food and Drug Administration works with interested individuals or groups and with the official standard-setting organizations—the U.S. Pharmacopeia, and the National Formulary—to develop improved laboratory methods and to revise or develop new standards as the necessary technology permits such changes. Meanwhile, the existing drug and manufacturing standards, drug surveillance system, batch testing requirements, and other standards such as bioavailability requirements, where needed, will assure safe and effective drugs of consistently high quality.

III. Establishment of Cost Limitations

Considering both cost and quality, the Department proposes to limit cost reimbursement for multiple source drugs under the health financing and service programs administered by the Department to the lowest cost at which chemically equivalent drugs are "generally available;" that is, marketed so as to be widely and consistently available to providers in the United States. This would be termed the "maximum allowable cost", or "MAC". While the greatest potential for savings exists with those drugs which are the most frequently prescribed, the policy would apply to all multiple-source drugs with significant price differentials. The MAC limitation would not apply when a prescriber certifies in writing that only a specific brand of drug is effective for or can be tolerated by a particular patient.

To develop and revise the list of drugs subject to MAC limitations, the Secretary proposes to establish a Pharmaceutical Reimbursement Board. The Board will consist of five regular Departmental employees, representing the principal program areas involved in developing and implementing the cost determination, who will devote part time to their duties as Board members. The Board will draw upon a Pharmaceutical Reimbursement Advisory Committee for advice and technical assistance. Members of the Advisory Committee will be selected from persons outside the Government to provide a broad range of knowledge, experience and judgment in the areas of pharmacy, pharmacology, medicine, pharmaceutical marketing, public health and consumer affairs.

Before establishing a MAC for any drug, the Board will request a statement from the Food and Drug Administration advising of any pending regulatory activity, including the establishment of a bioavailability requirement, that would warrant delay in applying a MAC to that drug.

Opportunities will be provided for individuals and organizations to submit relevant drug price information, propose additions to, revisions of, and deletions from the list, offer comments, and participate in oral hearings on proposed MAC limits.

It should be noted that the proposed MAC regulation does not establish procedures for fixing the actual amount of reimbursement to which providers will be entitled for dispensing drugs. Rather, it establishes procedures for setting a limit on what the individual program regulations and policies might otherwise provide. If the authorizing legislation for a particular program, or the program regulations or policies adopted or issued under that legislation, provide for a lower rate of reimbursement than the Departmental MAC regulation permits, then the program reimbursement rate, being lower, will necessarily control the actual payment.

IV. Acquisition Cost

The Department recognizes that published wholesale prices for drugs, including single-source drugs that would not be subject to the MAC policy, are frequently higher than prices actually paid by providers. Current regulations under Medicaid governing drug cost specify that cost is to be defined by the State agency. This has permitted a number of cost determination methods, resulting in significant cost differences among identical drugs. Some States reimburse providers on the basis of published wholesale prices; others pay on the basis of published prices less a volume discount to the program; still others pay the actual cost to the provider. Similar inconsistencies exist in other Department supported programs.

The Department believes that significant savings can be achieved in non-institutional settings by specifying payment for the cost portion of the provider's charge on the basis of actual acquisition cost. To promote economical purchases of multiple-source drugs subject to MAC limitations, the proposed regulation would allow retention by such providers of 25 percent of the difference between actual acquisition cost and the maximum allowable cost of any listed drug.

The Commissioner of the Social Security Administration, the Administrator of the Social and Rehabilitation Service, and the Assistant Secretary for Health will propose conforming regulations.

V. Price Information

The Department recognizes that the MAC policy and the acquisition cost policy proposed herein would not affect the prices charged by manufacturers for single-source drugs. The Department believes that additional cost savings can be achieved by providing current and comparative drug price information to physicians, pharmacists, and other health professionals. There is growing evidence that such information does promote cost-consciousness and economy in prescribing. Therefore, the Department plans to develop a simple and convenient format for communicating such information to drug prescribers and providers. The Department will conduct appropriate studies of the economic aspects and cost effectiveness of the proposed policies.

Therefore, the Secretary proposes to amend Subtitle A of Title 45 of the Code of Federal Regulations by adding a new Part 19, to read as set forth below.

PART 19—LIMITATIONS ON PAYMENT OR REIMBURSEMENT FOR DRUGS

Sec
19.1 Purpose.
19.2 Definitions.
19.3 Cost limitation.
19.4 Establishment of Pharmaceutical Reimbursement Board and Advisory Committee.
19.5 Determination of maximum allowable cost.
19.6 Review and revision of maximum allowable cost determinations.

Authority: Pub. L. 92-603, section 224, (40 U.S.C. 486c; 42 U.S.C. 1302, 1395f(b), 1395x(v), 1395hh; 42 U.S.C. 1396b(i)(1); 42 U.S.C. 242(b), 246(d)(e), 247b, 247c, 299d 42 U.S.C. 2688N-1); secs. 301, 311 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970; 84 Stat. 1349, 88 Stat 129; (42 U.S.C. 4571, 4577); secs. 409, 410, of the Drug Abuse Office and Treatment Act, 86 Stat. 81, 82 (42 U.S.C. 1176, 1177)

§ 19.1 Purpose.

This Part establishes Department of Health, Education, and Welfare procedures for determining drug costs and where applicable dispensing charges which the Department will use for the purpose of:

(a) Reimbursement to providers and health maintenance organizations under the Medicare program.

(b) Reimbursement to States under State administered health, welfare and social service programs.

EXHIBIT C

federal register

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PART IV

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

■

LIMITATIONS ON PAYMENT OR REIMBURSEMENT FOR DRUGS